

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MDL NO. 1:13-MD-2419-FDS

JUDGE RYA W. ZOBEL

This Document Relates to:

All Cases

**AMERIDOSE LLC'S OPPOSITION TO SAINT THOMAS ENTITIES' MOTION TO
COMPEL AMERIDOSE TO PRODUCE DOCUMENTS REQUESTED IN STES'
SECOND REQUEST FOR PRODUCTION**

Defendant Ameridose LLC ("Ameridose") opposes St. Thomas Entities' ("STEs") Motion to Compel Ameridose to Produce the documents it requested in its Second Request for Production of Documents. *See* NECC MDL Doc. 2188.

I. PROCEDURAL BACKGROUND

The STEs first propounded written discovery on Ameridose on March 9, 2015. It consisted of requests for admissions, interrogatories and requests for production ("first discovery requests"). Ameridose responded on April 8, 2015. *See* NECC MDL Doc. 1774. The STEs first discovery requests primarily sought documents and information regarding NECC's compounding, testing, and distribution of MPA, NECC's cleanrooms, and NECC's business operations.¹ In its responses to STEs first discovery requests – and in countless briefs filed with this Court, Ameridose clearly stated it had never compounded, tested, or distributed MPA. *See*

¹ *See e.g.*, RFP No. 10 ("All documents referring or relating to inspections of the NECC facility conducted by the FDA or MBP."), RFP No. 13 ("All documents referring or relating to sterility and fungal testing on MPA from 2006 to 2013."); *see also* ROG No. 8 ("Identify all time periods in which Ameridose compounded MPA at the NECC facility.").

e.g., NECC MDL Doc. 1774. The STEs were not satisfied with Ameridose's responses and objections. The parties met and conferred but could not resolve the issues.

The STEs served its Second Requests for Production of Documents ("second discovery requests") on Ameridose on April 27, 2015, and Ameridose responded on May 27, 2015. *See* NECC MDL Doc. 1910. STEs second discovery requests focused entirely on NECC's business operations and its compounding, testing, and/or distribution of MPA, seeking documents or information referring or relating to: "the compounding or manufacture of MPA by NECC," "the contamination of any NECC cleanroom," "any product compounded or manufactured in any cleanroom," "installation of NECC cleanrooms," and "to the cause or potential cause of MPA contamination at any NECC cleanroom." *Id.* Ameridose objected and responded to STEs' discovery requests, again explaining it never compounded, tested, or distributed MPA. *Id.*

The STEs also served a 30(b)(6) Deposition Notice to Ameridose on April 30, 2015 ("30(b)(6) Notice"). *See* NECC MDL Doc. 1809-2. The 30(b)(6) Notice also had a document request attached, which covered some of the same areas set forth in STEs' first discovery requests and second discovery requests. In response to the 30(b)(6) Notice, on May 5, 2015, Ameridose joined a Motion for Protective Order filed by certain individuals seeking protection from potential depositions pursuant to Fifth Amendment privileges. *See* NECC MDL Docs. 1823, 1824. Ameridose then filed a separate Motion for Protective Order as to both the deposition and document requests, to which the STEs opposed, and Ameridose replied. *See* NECC MDL Docs. 1879, 1943, 1980. The STEs also filed a Cross-Motion to Compel production of documents and order the deposition. *See* NECC MDL Doc. 1945. On July 31, 2015, the Court denied STEs' Cross-Motion to Compel Ameridose's production of documents without prejudice. *See* NECC MDL Doc. 2123, p. 20 (n. 14).

At the May 28, 2015 Status Conference, the Court requested position statements on the effect of the choice of law on pending discovery motions. On June 4, 2015, the Plaintiffs' Steering Committee ("PSC") filed its Position Statement and a supporting memorandum on June 22, 2015. *See* NECC MDL Docs. 1924, 2004. On June 25, 2015, Ameridose filed a Joinder in the PSC's Memorandum Regarding Choice of Law. *See* NECC MDL Doc. 2018. The STEs also filed their respective brief on choice of law issues on July 8, 2015.

On August 25, 2015, the STEs again filed a Motion to Compel seeking to compel Ameridose to produce the documents requested in STEs' second set of discovery requests (*see* NECC MDL Docs. 2188, 2189), to which Ameridose now responds.

II. FACTUAL BACKGROUND

Ameridose became part of the NECC fungal meningitis litigation in the Fall of 2012, at the same time Ameridose effectively ceased its business operations. *See, e.g.*, NECC MDL Docs. 1090, 1501. In compliance with preservation obligations pursuant to general case law and this Court's orders, Ameridose preserved various forms of documentary evidence relating to its business operations – both paper and electronic documents, as well as product inventories. *See* NECC MDL Doc. 1879-2. As Plaintiffs and even the STEs have acknowledged in multiple documents filed with this Court, Ameridose's business operations never involved the compounding, manufacture, testing, sale, or distribution of MPA. *See, e.g.*, NECC MDL Doc. 2189, p. 5 ("The Saint Thomas Entities seek documents relating to the compounding of MPA by NECC or the contamination of the MPA or any NECC cleanrooms.").

Soon after Ameridose was brought into the litigation, it became part of settlement discussions. Because of the settlement discussions and the order staying all discovery in the litigation – and because the projected cost to make Ameridose's preserved electronic data "searchable" for production purposes was estimated to be in excess of \$1,000,000 – the decision

was made not to process all of this data.² *See* NECC MDL Doc. 1879-2. The inaccessibility of these documents and the cost to process them has been well-known for over a year. *See, e.g.*, NECC MDL Docs. 1130 at pp. 3-4, 1262 at p. 4.

In late-2013 and early-2014, parties that had no intention of settling in the fungal meningitis litigation began to negotiate deposition and ESI protocols. Ameridose and the other Affiliated Defendants, in the midst of settlement discussions, did not participate in these negotiations regarding discovery protocols. In November 2014, Ameridose reached a settlement in the litigation. *See* NECC MDL Doc. 1694-5. The 30(b)(6) Notice and STEs' first motion to compel Ameridose to produce documents was not filed until on or about April 30, 2015, almost six months after settlement with the tort claimants was reached. On August 25, 2015, this Court dismissed all claims pending against Ameridose.³

The STEs remain the only parties seeking discovery from Ameridose despite the fact the STEs has itself expressly acknowledged on multiple occasions that it never bought any MPA from Ameridose, a fact which the STEs have acknowledged multiple times in multiple briefs. *See, e.g.*, NECC MDL Doc. 2180 ("Plaintiffs are attempting to hold the Saint Thomas Entities liable for these injuries because Saint Thomas Network owns one-half of Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), an outpatient ambulatory surgery center where NECC product was administered.").

² Only a small portion of Ameridose's preserved electronic data was processed.

³ As Ameridose is no longer a party, it is technically no longer subject to discovery under Federal Rules of Civil Procedure 33 and 34.

III. LEGAL ARGUMENT

A. The Court Should Defer Its Ruling On the STEs' Motion to Compel Until Choice of Law Has Been Decided.

There are two issues before the Court on the STEs' Motion to Compel – the choice of law issue and Ameridose's substantive response to the STEs' discovery issues. As the PSC and other parties have addressed in their respective choice of law briefs, the choice of law issue impacts directly the Court's analysis of the pending motions for protective order. "Depending on the choice of law, it may moot the need for this Court to resolve the many pending motions for protective order." NECC MDL Doc. 1924, p. 1. The STEs' sole purpose for continuing to harass Ameridose – who is no longer a party to the fungal meningitis litigation – for discovery, is because it claims to need this discovery for comparative fault purposes. "In support of their comparative fault affirmative defenses, the Saint Thomas Entities intend to prove that Ameridose owed an independent duty to Plaintiffs in this litigation and breached it." NECC MDL Doc. 2189, p. 3. Those comparative fault defenses only apply and the existence of such a duty only relevant under Tennessee law.

The PSC argued, and Ameridose joined, that under "the significant relationship test," Massachusetts law should apply to the issues of joint and several liability and comparative fault. NECC MDL Doc. 2004, p. 11. "Massachusetts law permits joint and several liability among joint tortfeasors, creates rights of contribution for joint tortfeasors whether they are joined in the original action or not, and permits comparative fault to be assessed only against parties who are present as defendants at trial." *Id.* If the Court decides that Massachusetts law applies to the issues of joint and several liability and comparative fault, "there is no need to conduct any 'comparative fault discovery' and therefore moot the motions seeking to take discovery from the settling defendants." NECC MDL Doc. 1924, p. 2. For this reason, the STEs' Motion to Compel

– and any attempt to discover documents and information from Ameridose is not yet ripe and should be stayed until this Court decides the pending choice of law issues.

B. Saint Thomas Entities Are Not Entitled to Requested Discovery.

The STEs first argue that they are entitled to discovery from Ameridose because the negligence claims asserted against the STEs and STOPNC “are clearly subject to comparative fault under Tennessee law.” NECC MDL Doc. 2189, pp. 7-8 (STEs’ Memo. in Support of its Motion to Compel Ameridose to Produce Documents). As Ameridose argued above, however, the choice of law issue has not yet been decided by this Court; and if Massachusetts law applies to these cases, comparative fault may not be asserted against Ameridose because it is not a party that will be present at trial.

Even if Tennessee law applies to the joint and several liability and comparative fault issues, the STEs are still not entitled to the documents they seek from Ameridose. First, none of the claims asserted by Plaintiffs or against the STEs implicate Ameridose as the – or one of the – entities that compounded, manufactured, tested, distributed, and/or sold MPA – the only drug at issue in this litigation. The STEs argue that fact is irrelevant to Ameridose’s discovery obligations and reference UniFirst, Liberty, Victory, and ARL BioPharma as examples of non-manufacturing entities from whom discovery has been procured. *See* NECC MDL Doc. 2189, p. 8. The STEs, however, neglect an important distinction: all of those entities have acknowledged in documents filed with this Court or in documents produced that – at the time the contaminated MPA was compounded, tested, and distributed – they were involved in the maintenance and/or functioning of the contaminated cleanroom and/or its component parts. At the time the contaminated MPA at issue in this litigation was compounded, tested, and distributed, Ameridose manufactured its products solely out of a facility 14 miles away from NECC’s Framingham facility. Even the overlapping ownership between NECC and Ameridose cannot

negate the fact that Ameridose has never been involved in compounding, testing, or distributing the only drug at issue in this litigation.

Second, Ameridose has never said “it had nothing to do with NECC.” NECC MDL Doc. 2189, p. 9. It has repeatedly acknowledged the overlapping ownership between the two entities and, in fact, responded to STEs discovery requests to that effect while also producing Ameridose’s Certificate of Organization and Certificate of Amendment, identifying the Managers as Barry Cadden and Gregory Conigliaro. *See* NECC MDL Doc. 1774. However, Ameridose has repeatedly asserted in briefs and affidavits that Ameridose was never involved in compounding, testing, distributing, or selling MPA. *See e.g.*, NECC MDL Docs. 1090, 1981. No discovery request can change that fact. And since MPA is the only drug at issue in this litigation, the STEs’ arguments that discovery from Ameridose is imperative to their defenses are totally baseless.

Finally, Ameridose was not a party to the discovery and ESI protocol discussions because, at the time those took place, Ameridose was actively engaged in settlement negotiations. In fact, Section IIA of the ESI Protocol specifically provides that a party may “object to the production of certain documents or ESI, including on the basis of relevance, undue burden, and/or inaccessibility.” NECC MDL Doc. 1087. In a new affidavit submitted with this Response, Ameridose sets forth in more detail the prohibitively high costs of processing and storing the unprocessed data, as well as continuing to store the email servers that were previously stored on an electronic database. *See* Affidavit of Matthew P. Moriarty, attached as Exhibit A. Ameridose has no resources to “process” all the preserved electronic media – the cost of which would exceed \$1,000,000. (*See* Defendant’s Motion for Protective Order, Doc. 1879, and Affidavit of Matthew Moriarty, Doc 1879-2.) It has effectively been out of operation since 2012

and its primary insurance carrier has no further obligation to Ameridose as a result of the settlement.

IV. CONCLUSION

For the foregoing reasons, Ameridose respectfully requests that this Court deny the Saint Thomas Entities' Motion to Compel Ameridose to Produce Documents requested in the STEs' Second Request for Production.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 8, 2015, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access the filing through the Court's system.

/s/ Ingrid S. Martin